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TITLE: Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Primary Care

PRINCIPAL INVESTIGATOR: Dr. Jeffrey A. Cigrang

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14. ABSTRACT Processes and documentation required for participant recruitment, consenting, administering and management of baselines measures, providing incentive payments, and obtaining and managing follow-up measures IAW IRB-approved protocol are all established and functioning effectively at our four data collection sites. Good team communication is achieved via weekly teleconferences. Forty-seven couples have been consented into the study and randomized to conditions. To date, we are meeting our projected goals for monthly enrollment. Anecdotal feedback from study therapists and participants indicates that the Marriage Checkup has been well-received.					
15. SUBJECT TERMS Military personnel, marital relations, couple therapy, primary care					
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Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants
in Military Primary Care
Year 1 Annual Report

Introduction

The most challenging community problems faced by senior military leaders are closely linked to the quality of marriage relationships. These include family violence, spouse maltreatment, and suicide. Despite the potential high costs of chronic marital distress, very few couples seek therapy. Thus, there is a substantial need in the military for early detection and preventative care for deteriorating couples. The Marriage Checkup (MC) addresses this issue by providing a less-threatening option for couples to seek early preventative care before they have begun to identify as distressed. In our pilot study the original MC was adapted for military couples and fit into the fast-paced environment of primary care. The results of the pilot study provide preliminary evidence suggesting that the MC can be effectively adapted to a military population, and successfully used by behavioral health consultants (BHCs) working in an integrated primary care clinic. The overall purpose of the current study is to build on the pilot study findings by conducting a randomized trial of the military-adapted MC delivered in primary care by BHCs. Specific Aims of the study are (1) conduct a randomized trial comparing MC for use in military primary care clinics to a wait list control condition, (2) examine the effects of MC participation on relationship health at post-treatment and a six-month follow-up period, and (3) determine whether the MC is successful at reaching couples at risk for marital deterioration who would otherwise be unlikely to seek traditional couple counseling. The randomized trial is being conducted at four military primary care clinics at Lackland, Randolph, Andrews, and Luke Air Force Bases.

Keywords

Military personnel, marital relations, couple therapy, primary care

Accomplishments

1. What were the major goals of the project?

	Timeline	
	Months	% complete
Major Task 1: Complete all preparatory work for project start.		
Subtask 1: Complete Research Protocol and Regulatory Documents		
Finalize baseline and follow-up measures; prepare data recording forms	1-3	100%
Establish process for participant incentive payments	1-3	100%
Refine eligibility criteria, exclusion criteria, screening protocol	1-3	100%
Finalize consent form & human subjects protocol	1-3	100%
Finalize methods for participant recruitment	3-6	100%
Purchase, establish use of IPADS for facilitating on-line baseline assessments	3-6	100%
Coordinate with Sites for flow chart for all study steps, web data collection and database requirements	3-6	100%
Coordinate with Sites for IRB protocol submission	1-6	100%
Coordinate with Sites for State University IRB review	1-6	100%

Coordinate with Sites for Military 2nd level IRB review (ORP/HRPO)	1-6	100%
Submit IRB amendments as needed	1-6	100%
Coordinate with Sites for annual IRB report for continuing review	1-6	100%
<i>Milestone Achieved: Local IRB approval at all research sites and Universities</i>	3	100%
<i>Milestone Achieved: HRPO approval for all protocols and local IRB approval through State Univ.</i>	6	100%
Subtask 2: Hiring and Training of Study Staff		
Coordinate with WSU Human Resources for job description design	1-2	100%
Advertise, interview and hire site-specific study coordinators	2-5	100%
Coordinate for space allocation for new staff at data collection sites	5-6	100%
Coordinate military base access for study coordinators	5-6	100%
Travel to sites to train IBHCs and study coordinators	7-9	100%
<i>Milestone Achieved: Study coordinators hired</i>	6	100%
<i>Milestone Achieved: IBHCs and study coordinators trained</i>	9 (Actual date: 6/23/16)	100%
<i>Milestone Achieved: All sites 100% ready for beginning RCT</i>	9 (Actual date: 6/23/16)	100%
Major Task 2: Begin RCT; Participant recruitment, intervention, assessment		
Conduct participant recruitment, baseline and 1-month follow-up assessments	10-15	100%
Conduct random assignment to MC or wait list stratified by site	10-15	100%
Ensure process for securing documents w/ personal identifiers in PI's office	10-15	100%
Conduct website data transfer, data quality checks, data base management	10-15	100%
Conduct weekly clinical supervision with IBHCs	10-15	100%
Conduct weekly supervision with study coordinators	10-15	100%
Submit amendments, adverse events and protocol deviations as needed	10-15	100%
Perform data analyses; share output and finding with all investigators	14-15	100%
Meet recruitment targets (3 couples per site per mo. /total 144 all sites per 12 mo.)	10-15	100%
<i>Milestone Achieved: RCT began successfully; 1st participant consented, enrolled</i>	10 (Actual Date: 2/16/2016)	100%

2. What was accomplished under these goals?

Protocol-level accomplishments:

- a. Processes and documentation required for participant consenting, administering and management of baselines measures, providing incentive payments, and obtaining and managing follow-up measures IAW IRB-approved protocol are all established and functioning effectively.
- b. A weekly teleconference attended by the entire team occurs on Friday at 11:00am EST. An additional teleconference for the Research Assistants is held weekly on Tuesday evening at 7:00pm EST. A third teleconference to provide clinical supervision to the therapists is held every other week on Monday at 9:00 EST.
- c. Local IRB approvals for the protocol were obtained from the PI's Universities (Wright State University and Clark University).
- d. Air Force IRB approval was received on 18 Nov 2015 (59 MDW IRB Reference Number: FWH20150096H).
- e. USAMRMC Office of Research Protections (ORP) Human Research Protections Office approved the protocol on 11 December 2015.
- f. Study progress was presented at the Ft Detrick IPR in April 2016. Based on feedback from the IPR panel, additional survey measures were added to the protocol to better assess (1) ability to involve couples who otherwise would not seek marriage counseling, and (2) whether participating in Marriage Checkup reduced home-work stress spillover. An amendment to add these measures was approved by the IRB on 2 May 2016.
- g. A total of 47 couples have been consented into the study and randomized to conditions as of 9/26/2016. To date, we are meeting our projected goals for monthly enrollment (see Appendix a). Enrollment slowed over the summer which we believe was at least partially due to the busy PCS season.
- h. Of the 52 individual participants who have reached the 1-month follow-up point, 47 have completed the survey and we have had communication with an additional three (see Appendix b.)

Site-Specific Accomplishments:

Randolph AFB & Lackland AFB, Texas.

- a. A Research Assistant, Rosalyn Pace, was hired on 18 November 2015 to support both sites in San Antonio and approved by the IRB on 20 January 2016 to be engaged in research.
- b. A second active-duty Air Force therapist, Capt Michael Ann Glotfeller, was recruited to the study at Lackland AFB. The IRB approved adding her to the protocol on 20 January 2016.

- c. Training on the Marriage Checkup protocol was conducted on December 17-18, 2015 for therapists and the research assistant at the two data collection sites in San Antonio (Randolph AFB, Lackland AFB).
- d. Participant recruitment/study advertisement efforts commenced in San Antonio in late January 2016.
- e. The first couple was successfully consented and randomized at Lackland AFB on 16 February 2016 and Randolph AFB on 13 April 2016.

Andrews AFB, Maryland.

- a. A Research Assistant, MSgt Rosalind Diyanni, was hired at Malcolm Grow Medical Center (Andrews AFB) on 4 March 2016 and approved by the IRB on 15 April 2016 to be engaged in research.
- b. Training on the Marriage Checkup protocol was conducted on 21-23 June 2016 at Andrews AFB.
- c. Lt Col Vanecek replaced Maj Jolyn Tatum as site PI. IRB approval to add Lt Col Vanecek to the protocol was obtained on 10 June 2016.
- d. The first couple was successfully consented and randomized at Andrews AFB on 11 July 2016.

Luke AFB, Arizona.

- a. A DoD Assurance of Compliance (#F50571) for the 56th MDG, Luke AFB, was approved by the Air Force Surgeon General Office on 18 May 2016.
- e. A Research Assistant, Gary Delado was hired at Luke AFB on 23 May 2016 and approved by the IRB on 10 June 2016 to be engaged in research.
- b. USAMRMC Office of Research Protections (ORP) Human Research Protections Office approved adding Luke AFB as a data collection site on 21 June 2016.
- c. The first couple was successfully consented and randomized at Luke AFB on 18 Aug 2016.

3. What opportunities for training and professional development has the project provided?

This project provided initial certification training to conduct Marriage Checkup for Primary Care to six Internal Behavioral Health Consultants (IBHCs) at four medical treatment facilities in the Air Force. The project also provides ongoing clinical supervision to the six IBHC. These six psychologists are quickly becoming the most experienced therapists in the world for implementation of a brief relationship intervention in the primary care setting. Their growing expertise will serve as the foundation in the future for effective dissemination and implementation of Marriage Checkup for primary care in the DoD.

4. How were the results disseminated to communities of interest? N/A
5. What do you plan to do during the next reporting period to accomplish the goals?
 - a. The first quarter of the second year will continue to focus on couple recruitment, enrollment, providing Marriage Checkup to those assigned to the treatment condition, clinical supervision of therapists, and gathering of follow-up surveys. The upcoming quarter will see the first of our six-month follow-up surveys.
 - b. Capt Glotfeller has expressed interest in helping establish a fifth data collection site for the study at Wright-Patterson AFB, Ohio. This would allow her to continue to serve as a study therapist, recruit couples at her new assignment, and help us achieve our enrollment goals. Normally this would not be feasible because the study budget for research assistants is limited to four sites. However, Wright Patterson AFB is located near Wright State University. I and my research assistant (Ashley Evans) can arrange to conduct the baseline consenting, measures completion, randomization, and scheduling for Capt Glotfeller. We will continue to explore this possibility after Capt Glotfeller gets established at Wright-Patterson AFB.
 - c. Over the next quarter we will continue to emphasize getting the Andrews AFB site ramped-up in couple recruitment. In the next several weeks we should have a “My Care” email blast sent out to all enrolled beneficiaries. Our experiences at other sites is that this method results in a significant increase in inquiries about the study from the community.
 - d. The San Antonio sites (Randolph and Lackland) have experienced a lull in recruitment over the summer months, compounded by Capt Glotfeller’s PCS. Our Research Assistant for San Antonio, Rosalyn Pace, is preparing an advertisement push for October that should achieve an increase in inquiries about the study for the Fall.

Impact

1. What was the impact on the development of the principal discipline(s) of the project?

The principle disciplinary field of the project is behavioral health services in an integrated primary care context. The first year of the project has increased our confidence that brief relationship assistance can be effectively incorporated into primary care. Anecdotal evidence indicates that the primary care therapists enjoy conducting Marriage Checkup and it is a positive experience for the couples who participate.

2. What was the impact on other disciplines?

The primary care clinic teams at our four data collection sites now have an in-house resource for referring patients who are interested in and may benefit from brief consultation for improving their marital relationship.

3. What was the impact on technology transfer? Nothing to report

4. What was the impact on society beyond science and technology? Nothing to report

Changes/Problems

1. In the original proposal Elmendorf AFB was to be one of our four data collection sites but our on-site partner received orders to PCS. We have since successfully recruited Luke AFB as replacement (see 15 December 2015 Quarterly Report for details).
2. Study start-up and couple recruitment at Andrews AFB has been slow (see 14 June 2016 Quarterly Report for details). The original site PI, Maj Jolyn Tatum, PCS'd in August from Andrews AFB. The new site PI Lt Col Vanecek is now taking a stronger leadership role in overseeing the Research Assistant and directly assisting with implementing a broad-based participant recruitment strategy. I hope to see improvements in our enrollment results over the next several months.
3. Capt Michael Ann Glotfeller, therapist and co-site PI at Lackland AFB, has PCS'd in September to Wright Patterson AFB, Ohio. Capt Glotfeller was invaluable at Lackland AFB as therapist and in working very closely with the Research Assistant in implementing a successful participant recruitment plan. The remaining site PI at Lackland AFB, Capt Fields, is dedicated to the project and will continue to function as the site lead and study therapist.

Products Nothing to report

Participants & Other Collaborating Organization

Name	Project Role	Nearest person month worked	Contribution to Project	Funding Support
Dr. Jeffrey A. Cigrang	PI	6	Served as the Principal Investigator for the Marriage Checkup (MC) project. Led effort to prepare, submit, & obtain final IRB approval. Worked with WSU Human Resources to complete all tasks necessary to post positions and hire research assistants. Oversaw work done by subcontract team at Clark University. Coordinated all aspects of study with Air Force.	NA
Dr. James Cordova	Co-PI	6	Primary responsibility for clinical supervision of study therapists. Oversaw all aspects of study at Clark University. Participated in weekly team teleconferences that include providing clinical supervision to therapists on MC.	U.S. Department of Health and Human Services
Capt. Abby Fields	Co-PI	6	Served as Air Force PI for IRB purposes. Served as therapist seeing couples enrolled in study at Wilford Hall Medical Center. Helped supervise Research Assistant (Rosalyn Pace). Participated in weekly team teleconferences.	NA
Capt. Michael Ann Glotfelter	AI	6	Served as therapist seeing couples enrolled in study at Wilford Hall Medical	NA

			Center. Helped supervise RA (Rosalyn Pace). Participated in weekly team teleconferences.	
Maj Elizabeth Najera	AI	6	Responsible for behavioral health integration in primary care for Air Force. Continues to provide guidance in weekly team teleconferences for implementing MC in primary care.	NA
Maj Jolyn Tatum	AI	6	Served as local PI at Andrews AFB until August 2016. Oriented new RA hired at her site. Participated in weekly teleconference.	NA
Lt Col Jodi Vanecek	AI	6	Served as local PI at Andrews AFB beginning August 2016. Serving as therapist seeing couples enrolled at Andrews AFB.	NA
Dr. Jennifer Mitchell	AI	6	Served as therapist seeing couples enrolled in study at Randolph AFB clinic. Helped supervise RA (Rosalyn Pace).	NA
Rosalyn Pace	Research Assistant	12	Served as RA for both Randolph and Lackland AFB sites in San Antonio. Helped development and implement participant recruitment plan. Served as primary POC for study in San Antonio. Scheduled, consented, completed baseline assessments for all participants.	NA
Rosalind DiYanni	Research Assistant	6	Served as RA for Andrews AFB. Helped development and implement participant recruitment plan. Served	NA

			as primary POC for study at Andrews AFB. Scheduled, consented, completed baseline assessments for all participants.	
Gary Delado	Research Assistant	6	Served as RA for Luke AFB. Helped development and implement participant recruitment plan. Served as primary POC for study at Andrews AFB. Scheduled, consented, completed baseline assessments for all participants.	NA
Tatiana Gray	Graduate Student	6	Primary team member responsible for use of on-line follow-up surveys. Monitors implementation, downloads de-identified results, converts to database for statistical analyses. Continues to assist Dr. Cordova on creation of the MC website and preparation of materials for training MC therapists. Prepared minutes from MC weekly teleconferences. Helped work out all logistics for conducting participant consenting, baseline assessment, randomization.	NA
Ashley Evans	Graduate Student	6	Had primary responsibility for revisions to IRB and other regulatory documents. Prepared drafts of quarterly reports. Took lead in orienting new RAs to study, assisted in completion of their IRB requirements. Scheduled	NA

			team teleconferences. Prepared documents required for HRPO submission. Led weekly teleconference for RAs	
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Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

No changes

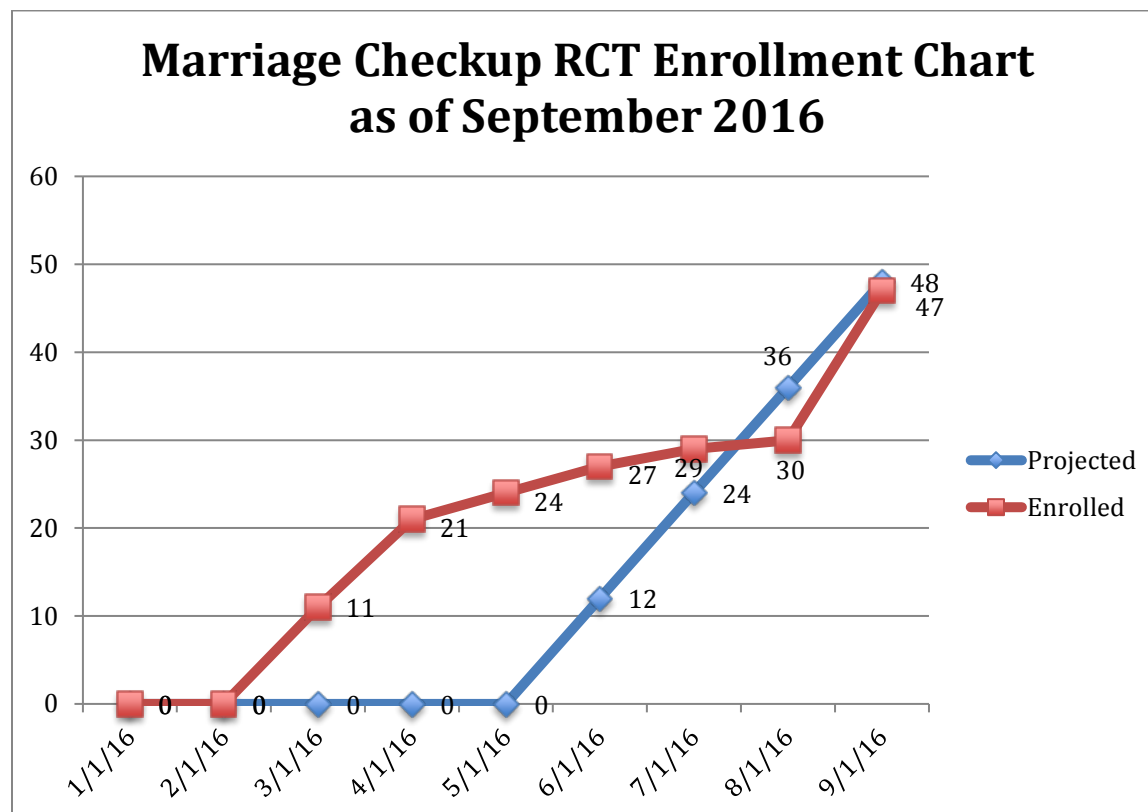
Special Reporting Requirements

See attached quad chart

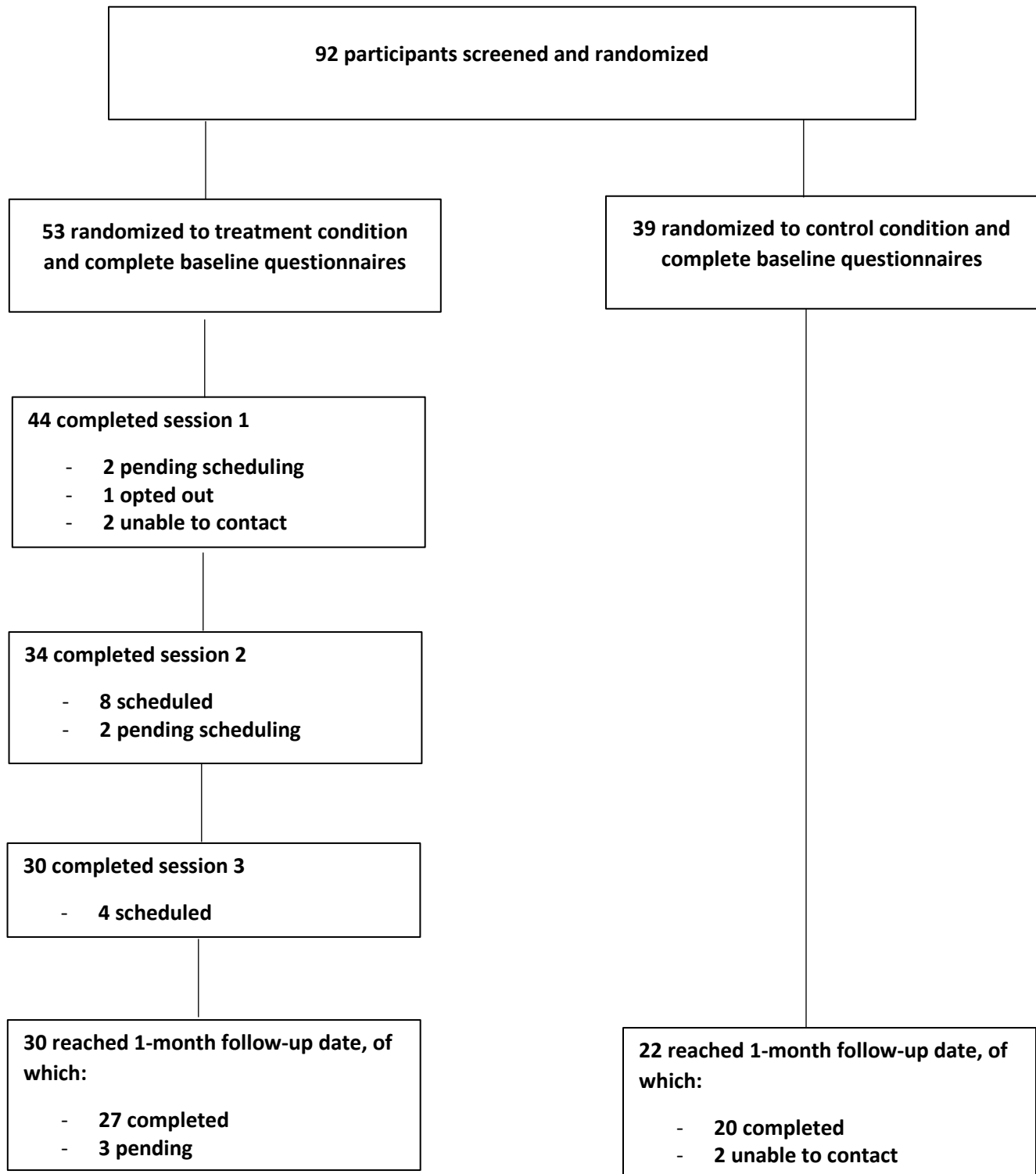
Appendices

- a. Participant Enrollment: Actual versus Projected.
- b. COHORT chart
- c. Quad Chart

Appendix a. Participant Enrollment: Actual versus Projected.



Appendix b. COHORT chart



Evaluation of a Brief Marriage Intervention for Internal Behavioral Health Consultants in Primary Care

Log #14227006, W81XWH-15-2-0025

PI: Jeffrey A. Cigrang, Ph.D., ABPP

Org: Wright State University

Award Amount: \$678,979



Study/Product Aim(s)

- Recruit service members and their partners who are in committed romantic relationships to participate in a Marriage Checkup (MC) delivered by Integrated Behavioral Health Consultants (IBHC) in primary care.
- Evaluate the efficacy of MC by comparing couples who receive MC to couples on a wait list control condition.
- Determine the ability of MC to attract military couples across a broad range of relationship functioning.
- Obtain qualitative data from IBHCs and couples after conclusion of the intervention study portion to measure MC implementation and factors impacting success.

Approach

Conduct a randomized clinical trial (N=250 couples) at four primary care clinics in the Air Force to evaluate effects of MC participation.



Accomplishments: (1) All four data collection sites up and running, fully staffed and with IRB, HRPO approvals. (2) quarterly participant recruitment goals met. (3) systems for tracking participant progress established. (3) obtaining 1 month follow-up surveys.

Timeline and Cost

Activities	CY	15	16	17	18
Preparatory work for project start					
Begin RCT; meet recruitment targets					
Continue RCT; report 6 mo. fu results					
Complete RCT and qualitative data collection					
Estimated Budget (\$678,979)		\$26,330	\$258,800	\$356,690	\$158,679

Updated: (30 September 2016)

Goals/Milestones

CY15 Goal – Complete preparatory work for project start

- ✓ Obtain IRB approval at all sites and Universities
- ✓ Hire site-specific study coordinators.

CY16 Goals – Begin RCT

- ✓ Obtain HRPO approval
- ✓ Complete training for study coordinators and therapists.
- ✓ Begin participant consenting; meet recruitment targets

CY17 Goal – Continue RCT

- Report findings to date from 6 month follow-up assessments

CY18 Goal – Complete RCT and qualitative data collection

- Report findings from 6 mo. fu assessments and qualitative interviews, focus groups

Budget Expenditure to Date

Projected Expenditure: \$678,979.00

Actual Expenditure: \$219,413.43 Through 8-31-2016